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5. 510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:

Advanced Medical Photonics
1384 Via Colonna Terrace
Davis, CA 95618
USA

JUN 17 2009

Contact Person:

Scott Porter
Director of Regulatory Affairs
Advanced Medical Photonics
1384 Via Colonna Terrace
Davis, CA 95618
Tel: (530) 219-4089
MedEngine@gmail.com

Summary Preparation Date: March 9, 2007

2. Device Name and Classification

Proprietary Name:	StrataPulse IPL System (Model STRATAPULSE TS and Model STRATAPULSE)
Common Name:	IPL System
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology. Product Code: ONF Regulation Number: 21 CFR 878.4810

3. Legally-marketed Equivalent Devices

Accelawave System: k082484

The StrataPulse IPL System (Model STRATAPULSE TS and Model STRATAPULSE) is substantially equivalent to other legally marketed flash lamp intense pulsed light devices (please reference, Section 12, Substantial Equivalence Discussion, Table 3, of this document).

4. Device Description

The StrataPulse IPL system is an intense pulsed light system. This device uses computer controlled power supply, xenon flash-lamp and band-pass filter to generate light pulses of prescribed duration, intensity and spectral distribution. The device is also equipped with cooling systems to maintain both the treatment head and the internal structure of the device at appropriate and safe temperatures. The light pulses or emission spectra provide therapeutic indications relevant to specific wavelengths emitted from the device. More specifically, the computer software regulates in a prescribed fashion the outflow of power from the power supply to the flash-lamp such that a flash of intense pulsed light is generated.

5. Indications for Use

Indications For Use (For Fitzpatrick Skin Types See Indications and Filters vs. Skin Types Chart Below):

The StrataPulse and StrataPulse TS IPL Systems are identical with regard to indications for use including recommended filters to be used with Fitzpatrick skin type. Both models are intended for medical use in the treatment of the following dermatologic conditions:

- Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen.
- Treatment of:
  - Moderate inflammatory acne vulgaris
  - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles).
  - Cutaneous lesions including scars
  - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, leg veins and venous malformations.

- Integrated thermal cooling is indicated for use in cooling the epidermis at the treatment site prior to, during and after light treatment in general aesthetic dermatologic and plastic surgery procedures to:
  - Reduce pain during light treatment (via partial anesthesia from cooling).
  - Reduce discomfort during and/or associated with light treatment
  - Minimize thermal injury, including thermal necrosis, to non-targeted skin and skin structures during and/or associated with light treatment, thus reducing possible complications such as scabbing, scarring, hype- and/or hypo pigmentation.
  - Allow the use of higher light or laser fluences for light treatments (such as for hair reduction and the treatment of vascular or pigmented lesions)
  - Reduce potential side effects of light treatment (such as for hair reduction and the treatment of vascular or pigmented lesions)

6. Performance Data

No performance data is required for this Class II device nor requested by the Food and drug Administration (Office of Device Evaluation). A database search has been conducted to evaluate any adverse effects of the device currently marketed.

No data submitted for section 807.92 6[(b)(1)(2)(3c)]. See attached documentation of adverse effects for predicate devices listed on Page 27 of this document.

Conclusion:

A comparison of the indications and the technical characteristics of the StrataPulse IPL system and the legally marketed device including the Accelawave System lead to the conclusion that the pertinent characteristics of the StrataPulse IPL system are substantially similar to the legally marketed devices. In this capacity the StrataPulse IPL system is substantially equivalent to device approved for marketing by the FDA and does not result in different performance or raise new questions of safety or efficacy.

Similarities/Differences	**Accelawave System**
Output Spectrum Characteristics	Similar
Output Pulse Characteristics	Similar, Programmable
Treatment Parameters	Similar, Programmable
Skin Cooling/Epidermal Cooling	Similar, Cold Contact Cooling

Side Effects:

In extreme cases, effects from treatment can include excessively red patches in the shape of the applicator head and blistering. If this occurs the tissue should be cooled and cared for as would normally be the case with burns to the skin, i.e. do not burst any blister formation, keep clean and cover until healed.

If blister form, they are usually intra-epidermal in nature and heal without scarring. Inappropriate management of blisters during the healing stage will increase the chance of scarring.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

Advanced Medical Photonics
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K090837
Trade/Device Name: StrataPulse IPL System (Model StrataPulse TS and StrataPulse)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: II
Product Code: ONF
Dated: May 28, 2009
Received: June 2, 2009

Dear Mr Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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4. Indications for Use

510(k) Number:

Device Name: StrataPulse IPL System (Model StrataPulse TS and StrataPulse)

Indications For Use (For Fitzpatrick Skin Types See Indications and Filters vs. Skin Types Chart Below):

The StrataPulse and StrataPulse TS IPL Systems are identical with regard to indications for use including recommended filters to be used with Fitzpatrick skin type. Both models are intended for medical use in the treatment of the following dermatologic conditions:

- Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen.
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  - Cutaneous lesions including scars
  - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, leg veins and venous malformations.

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  - Allow the use of higher light or laser fluences for light treatments (such as for hair reduction and the treatment of vascular or pigmented lesions)
  - Reduce potential side effects of light treatment (such as for hair reduction and the treatment of vascular or pigmented lesions)

Neil R P Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090837

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Indication and Filters vs. Skin Types for StrataPulse and StrataPulse TS

CONDITIONS	FILTER SETTINGS and WAVELENGTH RANGE	SKIN TYPES					
		I	II	III	IV	V	VI
Hair (course)		640-1200	640-1200	640-1200	640-1200	690-1200	N/A
Hair (fine)		640-1200	640-1200	640-1200	640-1200	690-1200	N/A
Acne Vulgaris		420-1200	420-1200	420-1200	420-1200	N/A	N/A
Pigmented Epidermal Lesions							
a) Dyschromia		510-1200	510-1200	510-1200	560-1200	N/A	N/A
b) Hyperpigmentation		510-1200	510-1200	510-1200	560-1200	N/A	N/A
c) Melasma		560-1200	560-1200	560-1200	560-1200	N/A	N/A
d) Ephelides		560-1200	560-1200	560-1200	560-1200	N/A	N/A
Cutaneous Lesions							
Scars		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
Cutaneous Vascular Lesions							
a) Port wine stain (child)		510-1200	510-1200	510-1200	N/A	N/A	N/A
b) Port wine stain (adult)		510-1200	510-1200	510-1200	N/A	N/A	N/A
c) Hemangiomas		560-1200	560-1200	560-1200	N/A	N/A	N/A
d) Telangiectasias		510-1200	510-1200	510-1200	N/A	N/A	N/A
e) Rosacea		560-1200	560-1200	560-1200	560-1200	N/A	N/A
i) Venous Malformations		560-1200	560-1200	N/A	N/A	N/A	N/A
Leg Veins							
a) Small		510-1200	510-1200	510-1200	N/A	N/A	N/A
b) Medium		560-1200	560-1200	560-1200	N/A	N/A	N/A
c) Large		560-1200	560-1200	560-1200	N/A	N/A	N/A

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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